

of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

(p) *510(k) statement* means a statement, made under section 513(i) of the act, asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in §20.61 of this chapter.

(q) *Class III certification* means a certification that the submitter of the 510(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

(r) *Class III summary* means a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

(s) *United States agent* means a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

(t) *Wholesale distributor* means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the

final delivery or sale of the device to the ultimate consumer or user.

(u) *Fiscal year* means the FDA fiscal year, which runs from October 1 through September 30.

(v) *FURLS* means the Food and Drug Administration's Unified Registration and Listing System.

(w) *FDA premarket submission number* means the number assigned by FDA to a premarket device submission, such as a Premarket Approval Application (PMA); Humanitarian Device Exemption (HDE); New Drug Application (NDA); Biologics License Application (BLA); de novo classification petition; or Premarket Notification (510(k)).

(x) *Importer* means, for purposes of this part, a company or individual in the United States that is an owner, consignee, or recipient, even if not the initial owner, consignee, or recipient, of the foreign establishment's device that is imported into the United States. An importer does not include the consumer or patient who ultimately purchases, receives, or uses the device, unless the foreign establishment ships the device directly to the consumer or patient.

(y) *Person who imports or offers for import* means, for purposes of this part, an agent, broker, or other entity, other than a carrier, that the foreign establishment uses to facilitate the import of its device into the United States.

[42 FR 42526, Aug. 23, 1977, as amended at 43 FR 37997, Aug. 25, 1978; 57 FR 18066, Apr. 28, 1992; 58 FR 46522, Sept. 1, 1993; 59 FR 64295, Dec. 14, 1994; 60 FR 63606, Dec. 11, 1995; 63 FR 51826, Sept. 29, 1998; 66 FR 59159, Nov. 27, 2001; 77 FR 45940, Aug. 2, 2012]

Subpart B—Procedures for Device Establishments

§ 807.20 Who must register and submit a device list?

(a) An owner or operator of an establishment not exempt under section 510(g) of the Federal Food, Drug, and Cosmetic Act or subpart D of this part who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration

and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one of these organizations when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments. The term “device” includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under section 351 of the Public Health Service Act. An owner or operator of an establishment located in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act shall register its name, places of business, and all establishments and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use, including any person who:

(1) Initiates or develops specifications for a device that is to be manufactured by a second party;

(2) Sterilizes or otherwise makes a device for or on behalf of a specifications developer or any other person;

(3) Repackages or relabels a device;

(4) Reprocesses a single use device that has previously been used on a patient;

(5) Acts as an initial importer as defined in §807.3(g), except that initial importers may fulfill their listing obligation for any device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer. Initial importers shall also be prepared to submit, when requested by FDA, the proprietary name, if any, and the common or usual name of each device for which they are the initial importer;

(6) Manufactures components or accessories that are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose, e.g. blood filters, hemodialysis tubing, or devices which of ne-

cessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient, e.g., a manufacturer of ophthalmic lens blanks.

(b) Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act.

(c) Registration and listing requirements shall not pertain to any person who acts as a wholesale distributor, as defined in §807.3(t), and who does not manufacture, repackage, process, or relabel a device.

(d) Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products, as defined in §1271.3(d) of this chapter, that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and cellular and tissue-based products with the Center for Biologics Evaluation and Research on Form FDA 3356 following the procedures set out in subpart B of part 1271 of this chapter, instead of the procedures for registration and listing contained in this part, except that the additional listing information requirements of §807.26 remain applicable.

(e) Owners and operators of establishments that manufacture devices licensed under section 351 of the Public Health Service Act as well as licensed biological products used in the manufacture of a licensed device must register and list following the procedures set out in part 607 of this chapter, instead of the procedures for registration and listing contained in this part.

[77 FR 45941, Aug. 2, 2012]

§ 807.21 How to register establishments and list devices.

(a) Owners or operators of establishments that are subject to the registration and listing requirements of this part must provide the following information to us using our electronic device registration and listing system, except as provided in paragraphs (b), (c), and (d) of this section: